

# Notice of Allowability

Application No.

09/684,890

Examiner

Stephen L. Rawlings, Ph.D.

Applicant(s)

ZENTGRAF ET AL.

Art Unit

1643

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06 July 2005.
2. ☒ The allowed claim(s) is/are 13-16, 23-25 and 30.
3. ☒ The drawings filed on 10 October 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 20050805.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

  
**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Vid Mohan-Ram, Ph.D. on August 5, 2005.

The application has been amended as follows:

In the claims:

Claim 18 has been canceled.

Claims 13 and 30 have been amended as follows:

13. (Currently Amended) A method for identifying the presence of a malignant cancer cell comprising: (a) providing a tissue biopsy sample; and (b) determining the level of expression in the tissue biopsy sample of the protein consisting of the amino acid sequence (SEQ ID NO: 2):

MAAAEGPVGDELWQTWLPNHVFLRLREGLKNQSPTEAEKPASSSL  
PSSPPPQLLTRNVVFGGLGELFLWDGEDSSFLVVRLRGPSGGGEEPAL  
SQYQRLLCINPPLFEIYQVLLSPTQHHVALIGIKGLMVLELPKRWGKNSE  
FEGGKSTVNCSTTPVAERFFTSSTSLTKHAAWYPSEILDPHVLLTSD  
NVIRIYSLREPQTPTNVILSEAEESLVLNKGRAYTASLGETAVAFDFGP  
LDAVPKTLFGQNGKDEVVAYPLYILYENGETFLTYISLLHSPGNIWKAVG  
SIAHASAAEDNYGYDACAVLCLPCVPNILVIATESGMLYHCVVLEGEED  
DHTSEKSWDSRIDLIPSLYVFECVELELALKLASGEDDPFDSDFSCPVKL

Art Unit: 1643

HRDPKCPSRYHCTHEAGVHSVGLTWIHKLHKFLGSDEEDKDSLQELST  
EQKCFVEHILCTRPLPCRQPAPIRGFWIVPDILGPTMICITSTYECLIWPLL  
STVHPASPPLLCTREDVEVAESSLRVLAETPDSFEKHRSILQRSVANPA  
FLKASEKDIAAPPPEECLQLLSRATQVFREQYILKQDLAKEEIQRRVKLLC  
DQKKKQLEDLSYCREERKSLREMAERLADKYEEAKEKQEDIMNRMKKL  
LHSFHSELPVLSDSERDMKKELQLIPDQLRHLGNAIKQVTMKKDYQQQK  
MEKVLSPKPTIILSAYQRKCIQSILKEEGEHIREMVKQINDIRNHVNF,

by ~~using~~ contacting the sample with the monoclonal antibody deposited under DSM ACC 2457, which binds to the protein, wherein the tissue biopsy sample comprises a malignant cancer cell if the expression level of the protein is greater than the expression level of that protein in healthy or normal control tissue.

30. (Currently Amended) A method for identifying the presence of a malignant cancer cell comprising (a) providing a tissue biopsy sample; and (b) determining the level of expression in the tissue biopsy sample of a protein consisting of the amino acid sequence depicted in SEQ ID NO: 2 ~~using~~ by contacting the sample with at least one of (i) a monoclonal antibody bearing the accession number DSM ACC 2457 and (ii) a recombinant or chimeric molecule that comprises at least six CDRs of the monoclonal antibody bearing the accession number DSM ACC 2457, which binds to the protein, wherein the tissue biopsy sample comprises a malignant cancer cell if the expression level of the protein is determined to be greater than the expression level of that protein in healthy or normal control tissue.

Art Unit: 1643

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1643

slr  
August 5, 2005



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER